

7.0 QUANTITATIVE SENTINEL SYSTEM
510(k) SUMMARY

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[807.92(a)1] Contact Information

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[807.92(a)2] Device Name and Classification

The proprietary name of the modified device to be introduced into interstate commerce is the Quantitative Sentinel System.

Common names include: QS, QS-2, QS System, QS/Perinatal System,, QS-FirstStep, and QS-Surveillance.

As indicated in the original premarket notification submission, the Quantitative Sentinel System is a class II device. To date no formal classification name has been issued for software based clinical information systems.

[807.92(a)3] Identification of Legally Marketed Equivalent Devices (Predicate Systems)

Predicate System	Manufacturer	k Number
Quantitative Sentinel System	Quantitative Medicine, Inc. (QMI) 200 Harry S. Truman Pkwy. Annapolis, MD 21401	k960109
Corometrics Model 400 Extended Surveillance and Alerts (Spectra 400)	Corometrics Medical Systems, Inc. 61 Barnes Park Road North Wallingford, CT 06492	

[807.92(a)4 & 807.92(a)5] Device Description & Intended Use

The Quantitative Sentinel (QS) System is a software application that is intended for use as clinical data management system (also referred to as a clinical information system -

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Version 4.04

CIS). The primary function of the system is the management of clinical data (whether manually or automatically acquired) for the purpose of providing integrated, ready and organized access to patient and/or clinical data that would normally be provided on paper records and/or separate clinical systems/devices. The QS System serves as a decision support tool as well as an electronic medical record. The QS System operates on off-the-shelf software and hardware. The device is intended for use in a hospital/clinical environment.

[807.92(a)6] Predicate Device Comparison of Technological Characteristics

Parameter	QMI's QS System Version 4.04.0	QMI's Predicate QS System (k960109)	Corometrics Spectra 400 (k852608)
Interface HIS, physiologic monitors	Yes	Yes	Fetal Monitors Only
Network architecture	Ethernet, Token Ring, or IBM Wireless LAN	Off-the-shelf computers and accessories	Proprietary
Hardware platform	Off-the-shelf computers and accessories	Off-the-shelf computers and accessories	Proprietary
Spectra Alerts	Yes	No	Yes

[807.92(b)1, 807.92(b)2 & 807.92(b)3] Performance Standards per the Food, Drug and Cosmetic Act

To date, no performance standards relating to devices of this type have been promulgated by the Food and Drug Administration.

[807.92(d)] Additional Information

The QS software and its environment has been extensively tested to meet its requirements and design. No clinical testing was necessary to demonstrate conformity to performance requirements.